

Attorney Docket No.: WARF-0003
Inventors: Dickerson and Helfand
Serial No.: 09/801,485
Filing Date: March 8, 2001
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The claims of the present application have been subjected to a Restriction Requirement under 35 U.S.C. §121 by the Examiner in this case as follows:

Group I, claims 27-37 drawn to a fusion protein comprising a mammalian interleukin-12 operably linked to an RGD-containing peptide, classified in class 514, subclass 2. It is believed that the restriction requirement contains a typographical error and that the proper claims for inclusion in Group I are claims 1-3;

Group II, claims 4-6, drawn to a nucleic acid sequence encoding a fusion protein, vectors, and host cells comprising the same, classifiable in class 435, subclass 320.1;

Group III, claim 7, drawn to a method for inhibiting growth of angiogenic, endothelial cells and $\alpha v \beta 3$ positive tumor cells, classified in class 514, subclass 2;

Group IV, claim 8, drawn to a method for decreasing toxic side effects associated with interleukin-12 administration in a mammal, classified in class 514, subclass 2; and

Group V, claims 9, drawn to a method for treating cancer in a mammal classified in class 514, subclass 2.

The Examiner suggests that the inventions are distinct each from the other. It is suggested that Groups III, IV, V and VI are directed to methods that are distinct both physically and

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functionally, and are not required one for the other. It is respectfully pointed out that the restriction requirement has defined only five groups. It is believed that a typographical error occurred and that only five groups are intended to be present in the restriction. It is further suggested that the Groups I and II are directed to products that are distinct both physically and functionally, and are not required one for the other. It is yet further suggested that Groups I and each of Groups III, IV, and V are related as product and processes of use. Groups II and each of Groups III, IV and V are suggested to be unrelated as having unrelated products and methods each of which is not required for the others.

The Examiner suggests that the Groups have acquired a separate status in the art as shown by their divergent subject matter, separate search requirements and differing classifications. Applicant respectfully traverses this restriction requirement.

MPEP §803 is quite clear; for a proper restriction requirement, it must be shown (1) that the inventions are independent or distinct AND (2) that there would be a serious burden on the Examiner if the restriction is not required. MPEP 802.01 defines "distinct" to mean that the "two or more subjects as disclosed are related, for example, as combination and part

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(subcombination) thereof, process and apparatus for its practice, process and product made there, etc., but are capable of separate manufacture, use, or sale, as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER."

As acknowledged by the Examiner, all of the claims are related to targeting Interleukin-12 to malignant endothelium. Thus, Applicants respectfully disagree with the Examiner's suggestion that designated groups are distinct as being novel and unobvious over each other as required by MPEP § 802.01; or that any additional search would be required by the inclusion of all of the groups. Accordingly, reconsideration and withdrawal restriction requirement is respectfully requested.

However, in an earnest effort to be completely responsive, Applicants hereby elect to prosecute Group I, claims 1-3 with traverse.

Respectfully submitted,

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